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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,261	09/08/2000	Jay N. Cohn	102258.288	3689

25270 7590 05/21/2002

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 05/21/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/658,261

Applicant(s)
Cohn et al.

Examiner
Ray Henley

Art Unit
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 6, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-38 and 42-49 is/are allowed.
- 6) ☒ Claim(s) 39-41 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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CLAIMS 1-50 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment filed May 6, 2002 has been received and entered into the application. Accordingly, claims 1, 2, 17-20, 33, 35 and 39 have been amended and claims 42-50 have been added.

Allowable Subject Matter

In light of the showing of unexpected results which occur when executing the presently claimed method, as explained by applicants at pages 2-4 of their amendment, claims 1-38 and 42-49 are deemed to be in condition for allowance.

Claim Rejection - 35 USC § 103

Claims 39-41 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn (U.S. Patent No. 4,868,179), already of record, for the reasons of record as set forth in the previous Office action dated December 5, 2001, as applied to claims 1-41.

With respect to new claim 50, it is believed that because the inclusion of an instruction means with pharmaceutical compositions is routine in the pharmaceutical art, the subject matter of claim 50 would have been obvious. The subject matter of the material printed on such means is taken to be no more than a statement of intended use which, when recited in composition- and/or kit-type claims do not impart any physical/material limitation to the composition or kit.

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Applicant's arguments have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

It is agreed that applicants have established that unexpected results do occur when the active agents are administered to a black population. However, such does not establish that the composition and/or kit itself possesses any unexpected property, i.e., a physical property that would not have been expected from the teaching of the prior art. Because a kit/composition is defined by what it is, rather than how it is to be used, a showing directed to the physical characteristics of the kit/composition itself would be necessary to impart patentable moment over the composition/kit suggested by the prior art.

Accordingly, for the reasons above, claims 39-41 and 50 are deemed to be properly rejected.


Applicants' amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.



RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1000

Henley; rjh
May 18, 2002